HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES 94828d

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

June 23, 2004

WARNING LETTER
CIN-WL-04-20224

SENT VIA FEDEX

Robert T. Ciesick
President/CEO
C & K Manufacturing & Sales Co., LLC
28825 Ranney Parkway
Westlake, OH 44145-1173

Dear Mr. Ciesick:

This letter concerns the manufacturing and marketing of Derm-Care™ AL Antimicrobial Lotion (Derm-Care™ AL). During an inspection of your firm at the above address on November 25 to December 2, 2003, investigators of the Food and Drug Administration (FDA) collected information and labeling, including printed promotional materials, about this product, which contains 0.15% benzalkonium chloride, identified on the label as the "ACTIVE INGREDIENT."

The labeling for Derm-Care™ AL includes such claims as: "long-lasting, broad spectrum antimicrobial lotion," "IMMEDIATELY KILLS PATHOGENS and keeps on killing them for up to 4 hours," and "up to a 99.9999% pathogen kill." In addition, the labeling represents this product as effective against "Norovirus" (sic), "Hepatitis A . . . B . . . [and] C," "Methicillin-resistant Staph aureus," among other pathogens. The labeling also states that the product's antimicrobial effectiveness is not diminished by contact with water or by handwashing ("does not lose effect, even if hands become wet," "remains after handwashing"). Based on these statements, Derm-Care™ AL is intended for over-the-counter (OTC) use to prevent diseases that may be caused by contact with pathogenic microorganisms. Similar representations are also included on your firm's Internet web site (www.ckmfg.com). These representations cause this product to be a "drug" as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

We are not aware of any evidence that a product formulated and labeled like Derm-Care™ AL was marketed in the United States on or before December 4, 1975. Nor is this product the subject of a final determination by FDA under Title 21 of the Code of Federal Regulations, Section 330.14 (21 CFR § 330.14). Accordingly, Derm-Care™ AL is not deferred to the OTC Drug Review. Further, we are not aware of any substantial scientific evidence establishing that Derm-Care™ AL is generally recognized among scientific experts as safe and effective for the uses stated in its labeling. Therefore, this product is a "new drug" as defined by section 201(p) of the Act. Since Derm-Care™ AL is not the subject of an approved new drug application, its marketing in the United States violates section 505(a) of the Act.

FDA is presently evaluating the safety and efficacy of skin protectants under the OTC Drug Review. A final monograph covering these products was published in the Federal Register (FR) of June 4, 2003 (68 FR 33362). This FR is available on FDA's Internet web site at http://www.fda.gov/cder/otcmonographs/Skin_Protectant/skin_protectant_FM_20030604.pdf. Pathogen skin barriers, like Derm-Care™ AL, are not included in this rulemaking, however.

OTC antiseptic cleansers and OTC first-aid antiseptics are also being evaluated under the OTC Drug Review. Tentative final monographs (TFMs) for these products were published in the Federal Register of June 17, 1994 (59 FR 31402) and July 22, 1991 (56 FR 33644), respectively. These TFMs are available at:

http://www.fda.gov/cder/otcmonographs/Antimicrobial/antimicrobial_antiseptic_TF_PR_19940617.pdf and;
http://www.fda.gov/cder/otcmonographs/Antimicrobial/antimicrobial_topical_first_aid_TF_PR_19910722.pdf.

Pathogen skin barriers, like Derm-Care™ AL, are not included in these TFMs.

FDA does not object to the marketing of products that comply with the formulation and labeling requirements described in final and tentative final monographs, along with any other regulations affecting these products. Marketing products in conformance with a TFM, however, is subject to the risk that a final monograph or rule may require reformulation and/or relabeling, or FDA approval through the "new drug" procedures of the Act (section 505).

The violations described above are not meant to be all-inclusive. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with the Act. Federal agencies are advised of the issuance of all Warning Letters pertaining to drugs and devices so that they may take this information into account when considering the award of contracts. We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

Please send a written response to this office within fifteen working days of receipt of this letter. Your response should describe the specific actions that you will take, or have taken, to correct the violations described in this letter. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations, including measures to revise the current claims about Derm-Care™ AL on the Internet. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed. Direct your response to Gina M. Brackett, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237.

Sincerely,

Carol A. Heppe
District Director
Cincinnati District

cc: Atlas Products of Ohio, LLC
6920 Hall Street
Holland, OH 43528.

cc: Atlas Products
8351 W. 185th Street
Tinley Park, IL 60477

cc: Hy-Gene Biomedical
7086 Olenhurst Court
Columbus, OH 43235